510 (k): K122481

510(k) SUMMARY

DEC 3 1 2012

PREPARATION DATE:	December 12, 2012
APPLICANT:	TearScience, Inc. 5151 McCrimmon Parkway, Suite 250 Morrisville, NC 27560 Tel: (919) 459-4815 Fax: (877) 468-5335
CONTACT PERSON:	Christy Stevens, OD, MPH Vice President, Clinical & Regulatory
DEVICE TRADE NAME:	LipiView® Ocular Surface Interferometer
COMMON NAME:	Ophthalmic Imaging Device
CLASSIFICATION NAME:	Ophthalmic Camera
DEVICE CLASSIFICATION:	Class II, 21 CFR 886.1120 and 886.1850
PRODUCT CODE:	HKI, HJO
PREDICATE DEVICE:	LipiView® Ocular Surface Interferometer Class II under 21 CFR 886.1120 and 21 CFR 886.1850; Product Code HKI, HJO; Applicant: TearScience, Inc.; Cleared under K091935 on October 23, 2009

DEVICE DESCRIPTION:

The LipiView® Ocular Surface Interferometer is a bench-top imaging device containing a computer system and electronics, chin rest and forehead rest, camera and zoom lens, illuminator and a touch screen display. The LipiView® Interferometer operates on the principle of white light interferometry and provides an interferometry color assessment of the tear film by specular reflection. The computer system captures a video image file that is recorded over time since the interference pattern changes as the tear film is distributed across the cornea during blinking. The video image of the ocular surface may be viewed on the computer screen display, in a printed report, or captured on video and exported to USB-attached storage or a mapped network drive.

The LipiView® Interferometer has been modified to software version 2.0, which includes changes to refine the interferometric color matching and blink detection methods used on interferometric images and to provide minor usability enhancements.

INTENDED USE:

The LipiView® Interferometer is intended to image the tear film. The LipiView® Interferometer is a prescription device for use by a physician during an in-office exam.

Indications for Use: The LipiView® Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented. Using these images, the LipiView® Interferometer measures the absolute thickness of the tear film lipid layer.

The LipiView® Interferometer with software version 2.0 has the same intended use as the predicate LipiView® Interferometer (K091935). In addition, the Indications for Use are similar to the predicate device, except that the Indications for Use have been expanded for the LipiView® Interferometer with software version 2.0 to include measurement of the tear film lipid layer thickness, as supported by performance testing. The expanded Indications for Use do not alter the intended use of the LipiView® Interferometer.

TECHNOLOGICAL CHARACTERISTICS:

The LipiView® Interferometer with software version 2.0 has the same fundamental scientific technology as the predicate device. As summarized below, most of the technological characteristics of the LipiView® Interferometer with the modification to software version 2.0 remain unchanged from the predicate device cleared under K091935. Minor differences in technology between the predicate device and the LipiView® Interferometer with software version 2.0 are described below.

Similarities: The LipiView® Interferometer with software version 2.0 and the predicate device share many of the same design features. Both devices have the same operating principle of real-time imaging of tear film dynamics based on the interference pattern from specular reflections. Both devices have an AC power source in compliance with IEC 60601 standards for electrical safety and electromagnetic compatibility. Both devices use the same Class I white light LED illuminator with exposure and level of illumination in compliance with ISO 15004-2 (Group 1 instrument) for safety. The patient contact materials for the chin and forehead rest and the method of disinfection are the same for both devices. Also, both devices have a digital video camera, personal computer with Microsoft Windows-based operating system, touchscreen display graphical user interface and computer accessory support for printing and data storage.

Furthermore, analogous software features on both devices include: password-protected user login; patient database; real-time video display to acquire tear film images; touchscreen user controls for camera and video playback; image acquisition process with storage of lossless AVI format video images; and tear film video playback and analysis.

Differences: Compared to the predicate device, the LipiView® Interferometer with software version 2.0 has refined interferometric color matching and blink detection methods used on interferometric images. In the predicate device, the interferometric color palette was theoretically derived; whereas in software version 2.0, the palette was developed and validated to a known standard for measurement of the tear film lipid layer thickness. Software version 2.0 also has enhancements for user convenience including: playback blink visualization; automated documentation of blinks; example tear film videos; adjustable video capture length; and ability to export video to an external USB storage device or mapped network drive.

PERFORMANCE TESTING:

The LipiView® Interferometer with software version 2.0 was developed and tested in compliance with design controls and the FDA Guidance documents for software validation in medical devices. To support the expanded Indications for Use, the LipiView® Interferometer was validated to physical phantoms representative of the pre-corneal tear film of a known thickness, as measured independently by ellipsometry. This testing demonstrated the

LipiView® Interferometer can make absolute measurements of the tear film lipid layer thickness by imaging interferometric colors. Test results showed the *in vivo* device measurement variability is 0.31 interferometric color unit (ICU) on average, or slightly less than one-third of the reporting precision of the device (1 ICU). Verification and validation test results demonstrated that the interferometric color matching performance of the LipiView® Interferometer with software version 2.0 is equal to or better than the predicate device. Tests also showed that version 2.0 had a higher overall percentage of correctly identified valid blink frames as compared to the predicate device. Enhancements for user convenience in software version 2.0 performed as intended and did not introduce any new risks to the device.

CONCLUSIONS:

The LipiView® Ocular Surface Interferometer with software version 2.0 has the same intended use and the same fundamental scientific technology as the predicate device. Performance testing demonstrates the LipiView® Interferometer with software version 2.0 is substantially equivalent in technological characteristics to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

DEC 3 1 2012

Tearscience, Inc.
c/o Christy Stevens, OD
VP, Clinical & Regulatory Affairs
5151 McCrimmon Parkway, Suite 250
Morrisville, NC 27560

Re: K122481
Trade/Device Name: LipiView Ocular Surface Interferometer
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: II
Product Code: HKI, HJO
Dated: December 18, 2012
Received: December 19, 2012

Dear Dr. Stevens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K122481 (To Be Assigned By FDA)

Device Name: LipiView® Ocular Surface Interferometer with Software Version 2.0

Indications for Use:

The LipiView® Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented. Using these images, the LipiView® Interferometer measures the absolute thickness of the tear film lipid layer.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) Number K122481

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